May 28, 2025

OPCOM Medical Inc.
Chinglin Huang
Regulatory Specialist
12F, No.6, JianKang Rd., Zhonghe Dist.
New Taipei City, 23586
TAIWAN

Re: K242699
Trade/Device Name: Flexible Ureteroscope (U-Scope)(2.8/1.2) (OMI161-2F28-CH12-US); Flexible Ureteroscope (U-Scope)(2.5/1.2) (OMI161-2F25-CH12-US); Images Systems (Camera-Controlled Unit) (OMI01M12)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FET
Received: May 5, 2025

Dear Chinglin Huang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242699

Device Name

Flexible Ureteroscope (U-Scope)(2.8/1.2) (OMI161-2F28-CH12-US);
Flexible Ureteroscope (U-Scope)(2.5/1.2) (OMI161-2F25-CH12-US);
Images Systems (Camera-Controlled Unit) (OMI01M12)

Indications for Use *(Describe)*

The Disposable Flexible Ureteroscope (U-Scope) is a sterile, single-use, flexible, digital video ureteroscope intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) via trans-urethral or percutaneous access routes. It can also be used in conjunction with endoscopic instruments via its working channel to perform various diagnostic and therapeutic procedures in the urinary tract.

Images Systems (Camera-Controlled Unit) is intended to provide power to and receive, process, display, and output recordings of images from compatible visualization devices, the intended medical indication will be defined by the connected visualization devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

1. **Submitter**

OPCOM Medical, Inc.

12F, No.6, JianKang Rd., Zhonghe Dist., New Taipei City 23586, Taiwan (R.O.C.)

2. **Contact Person**

ChingLin Huang, Regulatory specialist

Phone: +886 2 2221 7201 #1904

Email: hazel.huang@opcommedical.com

3. **Date Prepared**

May 27, 2025

4. **Trade Name**

Flexible Ureteroscope (U-Scope) (2.8/1.2) (OMI161-2F28-CH12-US);

Flexible Ureteroscope (U-Scope) (2.5/1.2) (OMI161-2F25-CH12-US);

Images Systems (Camera-Controlled Unit) (OMI01M12)

5. **Common Name**

Endoscope and accessories

6. **Classification Name**

Ureteroscope And Accessories, Flexible/Rigid

7. **Regulation Number**

876.1500

8. **Product Code**

FGB, FET

9. **Predicate Device**

K231878: Uretero1™ Ureteroscope System, STERIS Corporation

10. **Reference Device**

K221158: Single-Use Video Flexible Ureterorenoscope System, Guangzhou Red Pine Medical Instrument Co., Ltd

11. **Device Description**

The Flexible Ureteroscope (U-Scope) is a sterile, single-use, flexible, digital video ureteroscope. It contains a miniature CMOS camera, light-emitting diodes (LED) illumination module at the tip and an EEPROM in the handle to store use time. The tip of the U-Scope has a bending portion with 270° ± 15° bidirectional bend angle in the bending section. The U-Scope connects to the I through a separate electrical connector for sending image data and receiving LED power. The U-Scope has an inner working channel no less than 1.20mm for the infusion fluid and instrument passage with two access ports. The insertion tube distal tip OD is available in two size configurations: Flexible Ureteroscope (2.8/1.2) and Flexible Ureteroscope (2.5/1.2). Apart from the size, the endoscopes share a similar design and working length of the ureteroscope is 670 mm. The Luer Port working

lumen ID is 1.35mm and irrigation lumen ID is 1.3mm that is used for irrigation connection and accessory device access.

The reusable Images System (Camera-Controlled Unit) contains most electronics, including a power on/off button, touch screen, video processor, LCD, power management electronics and microcontrollers. The system includes the necessary hardware, software, and firmware to drive the endoscope CMOS camera and light-emitting diodes (LED), adjust live view images, capture images, save images to an external source, capture videos, save videos to an external source, manage saved image and files, and manage saved video files. The reusable Images System (Camera-Controlled Unit) has connectors for attaching and detaching the endoscope, external monitor, external memory, and DC power supply. The LCD has a touchscreen function for user interaction with the GUI to control the CCU functions. The display unit has a VESA mount incorporated into the rear of the enclosure for attachment to a cart or any existing customer mounting bracket that adheres to the same standard mounting pattern.

Both the reusable Images System (Camera-Controlled Unit) and the single-use Flexible Ureteroscope together complete the "Ureteroscope System" enabling a Flexible Ureteroscopy procedure to take place.

12. **Indications for Use**

The Disposable Flexible Ureteroscope (U-Scope) is a sterile, single-use, flexible, digital video ureteroscope intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) via trans-urethral or percutaneous access routes. It can also be used in conjunction with endoscopic instruments via its working channel to perform various diagnostic and therapeutic procedures in the urinary tract.

Images Systems (Camera-Controlled Unit) is intended to provide power to and receive, process, display, and output recordings of images from compatible visualization devices, the intended medical indication will be defined by the connected visualization devices.

13. **Indications for Use Comparison**

The subject device indications for use are similar to the predicate device. Both devices are intended for use for visualization in the urethra, bladder, ureter, calyces, and renal papillae via trans-urethral or percutaneous access routes to perform diagnostic and therapeutic procedures. Compared to the predicate device, the subject device indications include a separate description of the image processor function. This difference does not raise any different questions of safety or effectiveness.

14. **Technological Comparison**

Table 1 Comparison with Predicate Devices

Characteristic	Flexible Ureteroscope System	Uretero1™ Ureteroscope System
Manufacturer	OPCOM Medical. Inc.	Steris Corporation
Product Code	FGB, FET	FGB
Regulation Number	21 CFR 876.1500	21 CFR 876.1500

Indications for Use	The Disposable Flexible Ureteroscope (U-Scope) is a sterile, single-use, flexible, digital video ureteroscope intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) via trans-urethral or percutaneous access routes. It can also be used in conjunction with endoscopic instruments via its working channel to perform various diagnostic and therapeutic procedures in the urinary tract. Images Systems (Camera-Controlled Unit) is intended to provide power to and receive, process, display, and output recordings of images from compatible visualization devices, the intended medical indication will be defined by the connected visualization devices.	The single use Uretero1™ Ureteroscope System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.
Image sensor resolution	400*400	400*400
Tube size	OD: 2.5 /2.8mm Length:670mm	OD: 2.98mm Length:680mm
Working channel	ID: 1.2mm	ID: 1.2mm
Depth of field	5-50 mm	2-50 mm
Field of View	Nominal: 120°± 3°(diagonal) Measured: 110°± 3°(diagonal)	120°
Bending angle	Up / Down 270°±15°	Up 275° / Down 275°
Working hours	6 hours	4 hours
Illumination Source	5mm > 2600 lux 20mm > 700 lux 25mm > 500 lux	None disclose
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Waterproof	U-SCOPE: IPX7	None disclose
Operating conditions	10°C to 40°C 30%RH - 85%RH 50 KPa - 106 Kpa	17°C to 25°C 20%RH - 75%RH
Transport and Storage conditions	<70°C, < 95%RH 50 KPa - 106 Kpa	-20°C to 60°C 15%RH - 90%RH

LCD Size	12.1"	21.5"
Output Resolution	HDMI 1920 x 1080 30 fps Touch screen LVDS 1280 x 800 30fps	Full HD 1920(H) x 1080(V) pixels, 30Hz Touch screen
VESA	75 x 75 mm	100 x 100 mm
Electrical Power	12V/2A DC input 0.8A-1.2A AC 100-240V 50/60 Hz	12VDC, 5A AC 110V - 230V , 50 - 60 Hz
I/O	Right side: sensor and power connector Bottom side: USB, HDMI, DC Jack	USB, HDMI, power connector
Regulation Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18

Note:
Flexible Ureteroscope differs from its predicate device in some technical specifications, including insertion portion, Image sensor resolution, Depth of field and working hours. These differences do raise different questions of safety and performance. Flexible Ureteroscope has passes the performance testing.
Image system (Camera-Controlled Unit) differs from its predicate device in some technical specifications, including LCD Size. These differences do raise different questions of safety and performance. Image system (Camera-Controlled Unit) has passed the performance testing,

15. **Intended Use**

The Disposable Flexible Ureteroscope (U-Scope) is a sterile, single-use, flexible, digital video ureteroscope intended to be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) via trans-urethral or percutaneous access routes. It can also be used in conjunction with endoscopic instruments via its working channel to perform various diagnostic and therapeutic procedures in the urinary tract.

16. **Non-clinical Testing in Support of Substantial Equivalence Determination**

Non-clinical tests were conducted to verify that the proposed device meets all design specifications and is as safe and effective as the predicate device. The reference device was used to support the optical performance characteristics of the subject device.

Electrical Safety and Electromagnetic Compatibility

The test results demonstrated that the proposed device complies with the following standards:
IEC 60601-1:2005, IEC 60601-1:2005/AMD:2012, IEC 60601-1:2005/AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2014/AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Photobiological Safety

Photobiological safety of the subject device was assessed according to IEC 62471:2006.

Mechanical and Optical Performance

- Bending performance
- Working channel performance
- Flow rate
- Tensile and torsional strength
- Field of view (ISO 8600-3:2019 Method B)
- Direction of view (ISO 8600-3:2019)
- Resolution (ISO 8600-5:2020 Characteristic C)
- Noise and dynamic range
- Geometric distortion
- Image intensity uniformity

Software

Software Verification Test was performed to verify the software functions against its intended use.

Biocompatibility

Biocompatibility has been assessed according to:

-In Vitro Cytotoxicity tested according to ISO 10993-5:2009

-Skin Sensitization tested according to ISO 10993-10:2021

-Acute Systemic Toxicity tested according to ISO 10993-11:2017

-Penile Irritation Study tested according to ISO 10993-23:2021

-Vaginal Irritation Study tested according to ISO 10993-23:2021

-Pyrogen Study tested according to USP46:2023

Sterilization and shelf life

-Sterilization validation according to ISO 11135:2014

-Environmental conditioning (ASTM D4332-22) and simulated shipping distribution according to ASTM D4169-22

-Package integrity and device performance testing to support a three-year shelf-life for the Flexible Ureteroscope

17. **Conclusion**

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe and effective and substantially equivalent to the legally marketed predicate device.